

CLAIMS

1. A method for detecting the presence of infection by a pathogenic agent or a disease condition or a predisposition thereto, said method comprising determining the level of TLR-2 and/or TLR-4 or a homolog thereof wherein an elevated or reduced level of TLR-2 and/or TLR-4 or a homolog thereof is indicative of infection by the pathogenic agent or the presence of the disease condition or predisposition thereto.
2. The method of Claim 1 wherein the TLR-2 and/or TLR-4 or a homolog thereof is up-regulated.
3. The method of Claim 2 wherein the pathogenic agent is Hepatitis C virus (HCV).
4. The method of Claim 2 wherein the condition is cirrhosis.
5. The method of Claim 2 wherein the condition is hepatocellular carcinoma.
6. The method of Claim 1 wherein the TLR-2 and/or TLR-4 or homolog thereof is down-regulated.
7. The method of Claim 6 wherein the pathogenic agent is Hepatitis B virus (HBV).
8. The method of Claim 1 wherein the pathogenic agent is selected from *Salmonella*, *Escherichia*, *Klebsiella*, *Pasteurella*, *Bacillus* (including *Bacillus anthracis*), *Clostridium*, *Corynebacterium*, *Mycoplasma*, *Ureaplasma*, *Actinomyces*, *Mycobacterium*, *Chlamydia*, *Chlamydophila*, *Leptospira*, *Spirochaeta*, *Borrelia*, *Treponema*, *Pseudomonas*, *Burkholderia*, *Dichelobacter*, *Haemophilus*, *Ralstonia*, *Xanthomonas*, *Moraxella*, *Acinetobacter*, *Branhamella*, *Kingella*, *Erwinia*, *Enterobacter*, *Arozona*, *Citrobacter*, *Proteus*, *Providencia*, *Yersinia*, *Shigella*, *Edwardsiella*, *Vibrio*, *Rickettsia*, *Coxiella*, *Ehrlichia*, *Arcobacteria*,

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Peptostreptococcus, Candida, Aspergillus, Trichomonas, Bacterioides, Coccidiomyces, Pneumocystis, Cryptosporidium, Porphyromonas, Actinobacillus, Lactococcus, Lactobacillus, Zymononas, Saccharomyces, Propionibacterium, Streptomyces, Penicillum, Neisseria, Staphylococcus, Campylobacter, Streptococcus, Enterococcus and Helicobacter.

9. The method of Claim 1 wherein the pathogenic agent is selected from human immunodeficiency virus (HIV), Varicella-Zoster virus (VZV), herpes simplex virus (HSV), human papillomavirus (HPV), Hepatitis B virus (HBV), Hepatitis A virus (HAV), rhinovirus, echovirus, Coxsackievirus, cytomegalovirus, flavivirus, Ebola virus, paramyxovirus, influenza virus, enterovirus, Epstein-Barr virus, Marburg virus, polio virus, rabies virus, rubella virus, smallpox virus, rubeola virus, vaccina virus, adenovirus and rotavirus.
10. The method of Claim 1 wherein the level of TLR-2 or TLR-4 or homolog thereof is determined by the amount of mRNA encoding same.
11. The method of Claim 1 wherein the level of TLR-2 or TLR-4 or homolog thereof is determined at the protein level.
12. A method for monitoring a response to a therapeutic protocol directed against infection by a pathogenic agent or development of a disease condition said method comprising determining the level of TLR-2 and/or TLR-4 or a homolog thereof wherein the efficacy of the therapeutic response is determined by an elevation or reduction in the level of TLR-2 and/or TLR-4 or homolog thereof compared to pre-treatment levels and/or standardized control.
13. The method of Claim 12 wherein the TLR-2 and/or TLR-4 or a homolog thereof is up-regulated by the therapeutic protocol.

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14. The method of Claim 12 wherein the TLR-2 and/or TLR-4 or homolog thereof is down-regulated by the therapeutic protocol.
15. The method of Claim 12 wherein the pathogenic agent is Hepatitis C virus (HCV).
16. The method of Claim 12 wherein the condition is cirrhosis.
17. The method of Claim 12 wherein the condition is hepatocellular carcinoma.
18. The method of Claim 12 wherein the pathogenic agent is Hepatitis B virus (HBV).
19. The method of Claim 12 wherein the pathogenic agent is selected from *Salmonella*, *Escherichia*, *Klebsiella*, *Pasteurella*, *Bacillus* (including *Bacillus anthracis*), *Clostridium*, *Corynebacterium*, *Mycoplasma*, *Ureaplasma*, *Actinomyces*, *Mycobacterium*, *Chlamydia*, *Chlamydophila*, *Leptospira*, *Spirochaeta*, *Borrelia*, *Treponema*, *Pseudomonas*, *Burkholderia*, *Dichelobacter*, *Haemophilus*, *Ralstonia*, *Xanthomonas*, *Moraxella*, *Acinetobacter*, *Branhamella*, *Kingella*, *Erwinia*, *Enterobacter*, *Arozoa*, *Citrobacter*, *Proteus*, *Providencia*, *Yersinia*, *Shigella*, *Edwardsiella*, *Vibrio*, *Rickettsia*, *Coxiella*, *Ehrlichia*, *Arcobacteria*, *Peptostreptococcus*, *Candida*, *Aspergillus*, *Trichomonas*, *Bacterioides*, *Coccidiomyces*, *Pneumocystis*, *Cryptosporidium*, *Porphyromonas*, *Actinobacillus*, *Lactococcus*, *Lactobacillus*, *Zymomonas*, *Saccharomyces*, *Propionibacterium*, *Streptomyces*, *Penicillium*, *Neisseria*, *Staphylococcus*, *Campylobacter*, *Streptococcus*, *Enterococcus* and *Helicobacter*.
20. The method of Claim 12 wherein the pathogenic agent is selected from human immunodeficiency virus (HIV), Varicella-Zoster virus (VZV), herpes simplex virus (HSV), human papillomavirus (HPV), Hepatitis B virus (HBV), Hepatitis A virus (HAV), rhinovirus, echovirus, Coxsackievirus, cytomegalovirus, flavivirus, Ebola virus, paramyxovirus, influenza virus, enterovirus, Epstein-Barr virus, Marburg

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virus, polio virus, rabies virus, rubella virus, smallpox virus, rubeola virus, vaccinia virus, adenovirus and rotavirus.

21. The method of Claim 12 wherein the level of TLR-2 or TLR-4 or homolog thereof is determined by the amount of mRNA encoding same.
22. The method of Claim 12 wherein the level of TLR-2 or TLR-4 or homolog thereof is determined at the protein level.
23. A method for determining whether a subject will respond to therapeutic or prophylactic intervention of infection by a pathogenic agent or a disease condition said method comprising determining the level of TLR-2 and/or TLR-4 or a homolog thereof wherein the potential efficacy of the therapeutic intervention is determined by an elevation or reduction in the level of TLR-2 and/or TLR-4 or a homolog thereof compared to pre-treatment levels and/or standardized controls.
24. The method of Claim 23 wherein the TLR-2 and/or TLR-4 or a homolog thereof is up-regulated.
25. The method of Claim 24 wherein the pathogenic agent is Hepatitis C virus (HCV).
26. The method of Claim 24 wherein the condition is cirrhosis.
27. The method of Claim 24 wherein the condition is hepatocellular carcinoma.
28. The method of Claim 23 wherein the TLR-2 and/or TLR-4 or homolog thereof is down-regulated.
29. The method of Claim 28 wherein the pathogenic agent is Hepatitis B virus (HBV).

30. The method of Claim 23 wherein the pathogenic agent is selected from *Salmonella*, *Escherichia*, *Klebsiella*, *Pasteurella*, *Bacillus* (including *Bacillus anthracis*), *Clostridium*, *Corynebacterium*, *Mycoplasma*, *Ureaplasma*, *Actinomyces*, *Mycobacterium*, *Chlamydia*, *Chlamydophila*, *Leptospira*, *Spirochaeta*, *Borrelia*, *Treponema*, *Pseudomonas*, *Burkholderia*, *Dichelobacter*, *Haemophilus*, *Ralstonia*, *Xanthomonas*, *Moraxella*, *Acinetobacter*, *Branhamella*, *Kingella*, *Erwinia*, *Enterobacter*, *Aeromonas*, *Citrobacter*, *Proteus*, *Providencia*, *Yersinia*, *Shigella*, *Edwardsiella*, *Vibrio*, *Rickettsia*, *Coxiella*, *Ehrlichia*, *Arcobacteria*, *Peptostreptococcus*, *Candida*, *Aspergillus*, *Trichomonas*, *Bacterioides*, *Coccidiomyces*, *Pneumocystis*, *Cryptosporidium*, *Porphyromonas*, *Actinobacillus*, *Lactococcus*, *Lactobacillus*, *Zymomonas*, *Saccharomyces*, *Propionibacterium*, *Streptomyces*, *Penicillium*, *Neisseria*, *Staphylococcus*, *Campylobacter*, *Streptococcus*, *Enterococcus* and *Helicobacter*.
31. The method of Claim 23 wherein the pathogenic agent is selected from human immunodeficiency virus (HIV), Varicella-Zoster virus (VZV), herpes simplex virus (HSV), human papillomavirus (HPV), Hepatitis B virus (HBV), Hepatitis A virus (HAV), rhinovirus, echovirus, Coxsackievirus, cytomegalovirus, flavivirus, Ebola virus, paramyxovirus, influenza virus, enterovirus, Epstein-Barr virus, Marburg virus, polio virus, rabies virus, rubella virus, smallpox virus, rubeola virus, vaccinia virus, adenovirus and rotavirus.
32. The method of Claim 23 wherein the level of TLR-2 or TLR-4 or homolog thereof is determined by the amount of mRNA encoding same.
33. The method of Claim 23 wherein the level of TLR-2 or TLR-4 or homolog thereof is determined at the protein level.

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34. A method for predicting the outcome of a therapeutic protocol directed against infection by a pathogenic agent or development of a disease condition said method comprising determining the level of TLR-2 and/or TLR-4 or a homolog thereof wherein the efficacy of the therapeutic response is determined by an elevation or reduction in the level of TLR-2 and/or TLR-4 or homolog thereof compared to pre-treatment levels and/or standardized controls.
35. The method of Claim 34 wherein the TLR-2 and/or TLR-4 or a homolog thereof is up-regulated by the therapeutic protocol.
36. The method of Claim 34 wherein the TLR-2 and/or TLR-4 or homolog thereof is down-regulated by the therapeutic protocol.
37. The method of Claim 34 wherein the pathogenic agent is Hepatitis C virus (HCV).
38. The method of Claim 34 wherein the condition is cirrhosis.
39. The method of Claim 34 wherein the condition is hepatocellular carcinoma.
40. The method of Claim 34 wherein the pathogenic agent is Hepatitis B virus (HBV).
41. The method of Claim 34 wherein the pathogenic agent is selected from *Salmonella*, *Escherichia*, *Klebsiella*, *Pasteurella*, *Bacillus* (including *Bacillus anthracis*), *Clostridium*, *Corynebacterium*, *Mycoplasma*, *Ureaplasma*, *Actinomyces*, *Mycobacterium*, *Chlamydia*, *Chlamydophila*, *Leptospira*, *Spirochaeta*, *Borrelia*, *Treponema*, *Pseudomonas*, *Burkholderia*, *Dichelobacter*, *Haemophilus*, *Ralstonia*, *Xanthomonas*, *Moraxella*, *Acinetobacter*, *Branhamella*, *Kingella*, *Erwinia*, *Enterobacter*, *Arozoa*, *Citrobacter*, *Proteus*, *Providencia*, *Yersinia*, *Shigella*, *Edwardsiella*, *Vibrio*, *Rickettsia*, *Coxiella*, *Ehrlichia*, *Arcobacteria*, *Peptostreptococcus*, *Candida*, *Aspergillus*, *Trichomonas*, *Bacterioides*,

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Coccidiomyces, Pneumocystis, Cryptosporidium, Porphyromonas, Actinobacillus, Lactococcus, Lactobacillus, Zymononas, Saccharomyces, Propionibacterium, Streptomyces, Penicillum, Neisseria, Staphylococcus, Campylobacter, Streptococcus, Enterococcus and Helicobacter.

42. The method of Claim 34 wherein the pathogenic agent is selected from human immunodeficiency virus (HIV), Varicella-Zoster virus (VZV), herpes simplex virus (HSV), human papillomavirus (HPV), Hepatitis B virus (HBV), Hepatitis A virus (HAV), rhinovirus, echovirus, Cocksackievirus, cytomegalovirus, flavivirus, Ebola virus, paramyxovirus, influenza virus, enterovirus, Epstein-Barr virus, Marburg virus, polio virus, rabies virus, rubella virus, smallpox virus, rubeola virus, vaccina virus, adenovirus and rotavirus.
43. The method of Claim 34 wherein the level of TLR-2 or TLR-4 or homolog thereof is determined by the amount of mRNA encoding same.
44. The method of Claim 34 wherein the level of TLR-2 or TLR-4 or homolog thereof is determined at the protein level.
45. A method of treating a subject infected with a pathogenic agent or having a disease condition or having a predisposition thereto, said method comprising administering to said subject an effective amount of an agent which up-regulates or down-regulates the level of TLR-2 and/or TLR-4 or a homolog thereof.
46. The method of Claim 45 wherein the TLR-2 and/or TLR-4 or a homolog thereof is up-regulated by the agent.
47. The method of Claim 45 wherein the TLR-2 and/or TLR-4 or homolog thereof is down-regulated by the agent.

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48. The method of Claim 45 wherein the pathogenic agent is Hepatitis C virus (HCV).
49. The method of Claim 45 wherein the condition is cirrhosis.
50. The method of Claim 45 wherein the condition is hepatocellular carcinoma.
51. The method of Claim 45 wherein the pathogenic agent is Hepatitis B virus (HBV).
52. The method of Claim 45 wherein the pathogenic agent is selected from *Salmonella*, *Escherichia*, *Klebsiella*, *Pasteurella*, *Bacillus* (including *Bacillus anthracis*), *Clostridium*, *Corynebacterium*, *Mycoplasma*, *Ureaplasma*, *Actinomyces*, *Mycobacterium*, *Chlamydia*, *Chlamydophila*, *Leptospira*, *Spirochaeta*, *Borrelia*, *Treponema*, *Pseudomonas*, *Burkholderia*, *Dichelobacter*, *Haemophilus*, *Ralstonia*, *Xanthomonas*, *Moraxella*, *Acinetobacter*, *Branhamella*, *Kingella*, *Erwinia*, *Enterobacter*, *Arozoa*, *Citrobacter*, *Proteus*, *Providencia*, *Yersinia*, *Shigella*, *Edwardsiella*, *Vibrio*, *Rickettsia*, *Coxiella*, *Ehrlichia*, *Arcobacteria*, *Peptostreptococcus*, *Candida*, *Aspergillus*, *Trichomonas*, *Bacterioides*, *Coccidiomyces*, *Pneumocystis*, *Cryptosporidium*, *Porphyromonas*, *Actinobacillus*, *Lactococcus*, *Lactobacillus*, *Zymomonas*, *Saccharomyces*, *Propionibacterium*, *Streptomyces*, *Penicillium*, *Neisseria*, *Staphylococcus*, *Campylobacter*, *Streptococcus*, *Enterococcus* and *Helicobacter*.
53. The method of Claim 45 wherein the pathogenic agent is selected from human immunodeficiency virus (HIV), Varicella-Zoster virus (VZV), herpes simplex virus (HSV), human papillomavirus (HPV), Hepatitis B virus (HBV), Hepatitis A virus (HAV), rhinovirus, echovirus, Coxsackievirus, cytomegalovirus, flavivirus, Ebola virus, paramyxovirus, influenza virus, enterovirus, Epstein-Barr virus, Marburg virus, polio virus, rabies virus, rubella virus, smallpox virus, rubeola virus, vaccinia virus, adenovirus and rotavirus.

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54. The method of Claim 45 wherein the level of TLR-2 or TLR-4 or homolog thereof is determined by the amount of mRNA encoding same.
55. The method of Claim 45 wherein the level of TLR-2 or TLR-4 or homolog thereof is determined at the protein level.
56. The method of Claim 45 wherein the subject is selected from a human, non-human primate, livestock animal, companion animal, or avian species.
57. The method of Claim 56 wherein the subject is a human.
58. The method of Claim 45 wherein the agent is selected from a large or small chemical molecule, a nucleic acid molecule, a peptide, polypeptide, or protein, or RNAi.
59. The method of Claim 58 wherein the agent is an antisense molecule.
60. The method of Claim 58 wherein the agent is an antibody.
61. The method of Claim 58 wherein the agent is a sense molecule or antisense nucleic molecule or RNAi.
62. The method of Claim 58 wherein the antibody is a monoclonal antibody.
63. The method of Claim 58 wherein the antibody is a deimmunized antibody.
64. A pharmaceutical composition for use in treating infection by a pathogenic agent or a disease condition or a predisposition thereto, said composition comprising an antagonist or agonist of TLR-2 and/or TLR-4 or a homolog thereof and one or more pharmaceutically acceptable carriers and/or diluents.